

Appl. No. : 10/628,880  
Filed : July 28, 2003

## REMARKS

In the Office Action, Claims 27-34 and 78-106 were rejected over the prior art as discussed below. In this Amendment, Claims 27, 82, and 90 have been amended, Claim 107 has been added, and Claim 92 has been canceled. Claims 27-34, 78-91, and 93-107 remain pending for further consideration.

### Rejections Under 35 U.S.C. § 112

Claims 27-34 and 78-91 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant disagrees with the rejection, for example, because Claim 82 does not include the phrase “the distal portion is configured to bend at least 90 degrees.” Therefore, the rejection of Claim 82-91 is traversed. Moreover, because the phrase objected to by the examiner is supported in the specification as filed. Nevertheless, to expedite prosecution, Applicant has amended Claims 27 to eliminate this phrase. Therefore, the rejection of Claims 27-34 and 78-91 should be withdrawn.

### Rejections Under 35 U.S.C. § 103

In the Office Action, the claims were rejected as obvious in view of distinct sets of references, i.e., based on (1) U.S. Patent No. 6,165,183 issued to Kuehn et al. (Kuehn) in view of U.S. Patent No. 4,777,951 issued to Cribier et al. (Cribier) and (2) U.S. Patent No. 5,626,588 issued to Sauer et al. (Sauer) in view of Cribier. Though Applicant disagrees with these rejections, the claims have been amended to expedite allowance as set forth below. The pending claims are in condition for allowance.

#### *Kuehn and Cribier*

In the Office Action under 35 U.S.C. § 103(a), Claims 27-29, 31-34, 78-84, 86-91, and 102-103 were rejected as being obvious over Kuehn in view of Cribier.

Claims 27-29, 31-34, 78-84, and 86-91 were rejected as being obvious over Figures 20 and 21 of Kuehn in view of Cribier. Applicant disagrees with this rejection. For example, Applicant disagrees with the Examiner assertion that the grasper tube 441 is an “anchor zone.” Office Action, page 4. However, to expedite allowance Applicant has incorporated the limitation

of Claim 92 into Claim 27. Claim 27 as amended recites catheter for accessing the heart and engaging a heart valve, comprising:

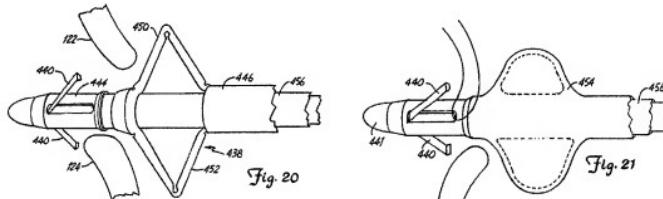
an elongate flexible body, having a proximal end and a distal end, *the elongate flexible body having housed therein a fastening material configured to suture two heart leaflets together;*

an anchor zone on a distal portion of the flexible body; and

at least one tissue manipulator carried by the flexible body proximally of the anchor zone, the tissue manipulator having a fixed end and a free end, the free end being moveable to an extended position in which the free end is proximal of the fixed end, the tissue manipulator being disposed at an angle not more than 90 degrees with respect to the elongate flexible body when in the extended position;

wherein the distal portion is configured to extend at least into an anatomical region adjoining the heart valve and the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator can be positioned at the valve.

This is not taught or suggested by Kuehn, which is directed to a device that includes a gripper 438 with a plunger 446 that is used to direct leaflets of the valve to gripper arms or "graspers" 440. Graspers 440 are mounted on a grasper tube 441.



Kuehn teaches that any structure to position the graspers 440 relative to the valve leaflets should be located proximally of the graspers 440. In particular, the plungers 446, 454 are used to bring the leaflets into engagement with the graspers 440. Kuehn states that "as plunger 446 or 454 reaches a certain position relative to graspers 440 so that graspers 440 are within reach of leaflets 122, 124, shaft 456 is pulled back to retract graspers 440, which clasp leaflets 122, 124 between graspers 440 and grasper tube 441." Kuehn at 9:61-65. Thus, Kuehn teaches locating proximally of the graspers 440 a structure that is for bringing the graspers 440 into a position in which the graspers 440 engage the leaflets. There is no suggestion of housing within any of the structures of Figures 20 or 21 a fastening material configured to suture two heart leaflets together.

For at least these reasons Claim 27 and Claims 28-29, 30-34, and 78-81 which depend therefrom are distinguishable over Kuehn and Cribier.

Appl. No. : 10/628,880  
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Similarly, Claim 82 now recites a catheter for performing a procedure on the heart, comprising:

an elongate flexible body, having a proximal end, a distal end and a length sufficient to reach the heart from a femoral vein access;  
at least one tissue manipulator on the elongate, flexible body; and  
an elongate, flexible distal portion comprising an anchor zone, the distal portion extending distally of the tissue manipulator;  
*a fastening material adapted for use in suturing two leaflets of a heart, the fastening material being housed within the distal portion;*  
wherein the distal portion is sufficiently flexible and long that it can extend through the mitral valve and into the left ventricular outflow tract and the anchor zone is configured to orient and anchor the catheter while the tissue manipulator is positioned at a leaflet of the mitral valve.

There is no suggestion of a catheter comprising a fastening material adapted for use in suturing two leaflets of a heart, the fastening material being housed within any of the structures of Figures 20 or 21 a fastening material configured to suture two heart leaflets together. For at least the reasons set forth above, Claims 82 and Claims 83-85, 86-91, 102, and 103 which depend from Claim 82 are distinguishable over Kuehn and Cribier.

***Sauer, Cribier, and Laufer***

Claims 27, 32, 92-97, 99-102, and 104-106 were rejected as being obvious over Sauer in view of Cribier and Claims 98 and 103 were rejected as being obvious over Saur and Cribier and further in view of U.S. Patent No. 5,609,598 issued to Laufer et al. (Laufer). Applicant disagrees with these rejections but has made certain amendments solely to expedite allowance. For example, Claim 27 now recites a catheter for accessing the heart and engaging a heart valve, comprising:

an elongate flexible body, having a proximal end and a distal end, the elongate flexible body having housed therein a fastening material configured to suture two heart leaflets together, an anchor zone on a distal portion of the flexible body; and  
*at least one tissue manipulator carried by the flexible body proximally of the anchor zone, the tissue manipulator having a fixed end and a free end, the free end being moveable to an extended position in which the free end is proximal of the fixed end, the tissue manipulator being disposed at an angle not more than 90 degrees with respect to the elongate flexible body when in the extended position;*  
wherein the distal portion is configured to extend at least into an anatomical region adjoining the heart valve and the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator can be positioned at the valve.

In contrast, Sauer is directed to a trocar wound closure device. This device is used to close a puncture that extends from the skin 124 through a layer of fat 126 and through facia 128.

FIG. 14

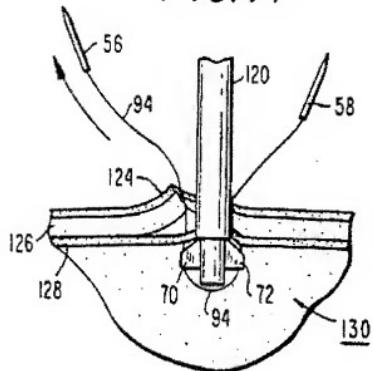
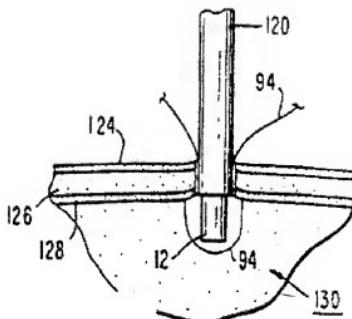


FIG. 15



Applicant initially notes that this is a very different application than that for which the present application is capable of use, e.g., for suture flaps of a valve of a beating heart. In addition, while Applicant may not necessarily agree that the needle carriers 70, 72 are tissue manipulators as previously recited in the claims, these structures are required to have the above-illustrated tapered configuration. Sauer states that “[t]he taper of the needle carriers will cause retraction of the needle carriers into the body of the trocar wound closure device as the device is withdraw as shown in FIG. 15.” Sauer 5:31-33. Apparently unless this tapered construction is provided, the needle carriers 70, 72 cannot be removed from the patient. Thus, the recitation of Claim 27 is not taught or suggested by Sauer.

For the reasons set forth above, Claim 27 is distinguished over the combination of Sauer and Cribier. Accordingly, Applicant requests that the rejection of Claim 27 and of Claims 32, 93-97, 99-102, and 104-106 which depend directly or indirectly from Claim 27 be withdrawn.

Also, the rejection of Claims 98 and 103 in view of Sauer, Cribier, and Laufer should be withdrawn at least for the reasons set forth above.

Accordingly, all of the pending claims are not in condition for allowance and such action is respectfully requested.

Appl. No. : 10/628,880  
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No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

**CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Andrew M. Douglas at (949) 721-7623 to resolve such issue(s) promptly.

Appl. No. : 10/628,880  
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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